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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,485	09/27/2006	James Farina	1702 WO/US	1304
7590 12/10/2008 Christine Rebman Cooke			EXAMINER	
Mallinckrodt			NIESZ, JASON KAROL	
675 Mcdonnell Boulevard P O Box 5840			ART UNIT	PAPER NUMBER
St Louis, MO 63134			3751	
			MAIL DATE	DELIVERY MODE
			12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/594,485 FARINA, JAMES Office Action Summary Examiner Art Unit JASON K. NIESZ 3751 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 07 October 2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1.8-13.16.17.23.24 and 26-28 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1,8-13,16,17,23,24 and 26-28 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☑ The drawing(s) filed on 27 September 2006 is/are: a) ☑ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date \_\_\_\_\_\_.

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

## Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1, 8-13, 16, 17, 23, 24 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madaio (US Patent 3,853,157) in view of Cullen (US Patent 3,371,825), Baldwin (US Patent 4,863,429) and Macarone et al. (US Patent 3,506,005).

In Re claims 1 and 12 with reference to Figure 1 Madaio discloses an apparatus for storing and dispensing a material from a pressurized container (6) comprising a reciprocating dispensing valve (11), said dispensing valve having a stem with a distal end protruding from the container (11) and a proximal end extending into the pressurized container (9). Madaio further discloses a bag (6) and pressurizing gas (2). Madaio further discloses a syringe (46) and a removable adaptor (29). Madaio also discloses a hollow valve stem (37) having a closed end (13) and a covered opening (36). With reference ton Figure 5 Madaio discloses a moving the valve stem into the pressurizing container to uncover the opening.

Madaio doesn't disclose a desiccant material in the pressurizing gas, an on/off locking member for the svringe, or a gasket covering the opening in the valve stem.

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Cullen discloses a dispenser comprising a pressurized gas containing a drying agent (Column 4, lines 13-16), which acts to remove water to prevent the breakdown of the propellant.

Baldwin in Figure 1 discloses a syringe having an on/off locking member (81) attached to the syringe through a luer lock (79).

Macarone in Figure 14 discloses a pressurized container (150) having a reciprocating valve (188) comprising a valve stem (190) which is closed at the end but has a covered opening (198) which is covered and sealed by a circular gasket (180), which is engaged slidingly with the valve stem.

Therefore, it would have been obvious to modify the Madaio apparatus as follows: by including the desiccant material from Cullen to the propellant gas, in order to prevent the breakdown of the propellant and the corrosion of the container, by adding the on/off locking member from Baldwin, in order to allow a more precise control of the filling operation, and by using a circular gasket to seal the circumferential opening in the valve stem, as taught by Macarone, in order to provide a more secure seal than that provided by the clearance between the valve stem and the valve head.

In Re claims 8 and 9 with reference to Figure 1 Madaio discloses a valve connector (15) having a central opening (9) connected to the bag and the valve stem. Madaio further discloses a biasing spring (19) which biases the valve stem outwardly from the pressurized container.

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In Re claim 10 with reference to Figure 1 Madaio discloses an adaptor (29) comprising two female sockets (the socket holding the valve stem: 11, and the socket holding the syringe: 43) connected by a material flow passageway (41).

In Re claim 11 with reference to Figure 1 Madaio discloses an adaptor (29) comprising two female sockets (the socket holding the valve stem: 11, and the socket holding the syringe: 43) connected by a material flow passageway (41).

In Re claim 13 with reference to Figure 1 Madaio discloses a reciprocatably actuated piston (51).

In Re claim 16 the apparatus applied to claim 1 above during ordinary use and operation necessarily performs the method of claim 16 with the exception of activating the on/off member for permitting the flow and activating the on/off member to isolate the material. Both of these steps are obvious applications of said on/off member and would be known by one of ordinary skill in the art as a common sense usage of said on/off member.

In Re claim 17 Madaio in view of Cullen, Baldwin, and Macarone as applied to claim 16 above discloses all the limitations, but doesn't disclose the step of replacing the stem of the syringe with a needle, activating the on/off member to the on position, and expelling material from the syringe chamber into a closed system. The examiner notes that the steps of replacing a syringe stem with a needle and dispensing its contents into a closed system (a human body for example) are so obviously associated with a syringe as to be substantially inherent. Furthermore, the step of activating the

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on/off locking member to the on position is inherently required to dispense any material held in the syringe.

In Re claim 23 with reference to Figure 1 Madaio discloses a valve connector (15) having a biasing spring 919) which biases the valve stem outwardly from the pressurized container.

In Re claim 24 with reference to Figure 1 Madaio discloses an adaptor (29) comprising two female sockets (the socket holding the valve stem: 11, and the socket holding the syringe: 43) connected by a material flow passageway (41).

In Re claim 26 the examiner notes that it would have been an obvious matter of design choice to use the Madaio in view of Cullen, Baldwin and Macarone apparatus to dispense any material desired by a user.

In Re claim 27 Madaio in view of Cullen, Baldwin, and Macarone as applied to claim 16 above discloses all the limitations, but doesn't disclose the step of replacing the stem of the syringe with a needle, activating the on/off member to the on position, and expelling material from the syringe chamber into a closed system. The examiner notes that the steps of replacing a syringe stem with a needle and dispensing its contents into a closed system (a human body for example) are so obviously associated with a syringe as to be substantially inherent. Furthermore, the step of activating the on/off locking member to the off position is the final step in the method as applied to claim 16 and that activating said on/off locking member to the on position is inherently required to dispense any material held in the syringe.

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In Re claim 28 with reference to Figure 1 the use of the reciprocatable syringe piston (51) to expel the contents of the syringe is inherent in the function of the Mandaio apparatus.

### Response to Arguments

 Applicant's arguments with respect to the Cullen and Baldwin references filed 10/07/2008 have been fully considered but they are not persuasive.

The Cullen reference teaches the use of a drying material, (desiccant) to at least in part prevent the breakdown of a propellant gas by water contamination. The use of such a material in the Madaio reference would obviously require the drying material to be placed in the propellant gas. Desiccants are commonly known in the art and it would be within the knowledge of one of ordinary skill in the art and taught by Cullen to place a known desiccant material in the propellant gas in the Madaio apparatus.

The Baldwin apparatus teaches the use of an on/off device in conjunction with a syringe. The use of said device to permit material to enter and exit the syringe when desired and to disallow such movement at all other times would be obvious to one of ordinary skill in the art.

 Applicant's arguments with respect to the slidable gasket have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON K. NIESZ whose telephone number is (571)270-3920. The examiner can normally be reached on mon-fri 9-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jason K Niesz Examiner Art Unit 3751

/Timothy L Maust/ for Gregory Huson, SPE of Art Unit 3751